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Senior Vice President and
General Counsel

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August 18, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Dkt. No. 00N-1351/Use of the Term "Fresh"

Dear Sir/Madam:

This letter is submitted by Tropicana Products, Inc. (Tropicana) in response to the Food and Drug Administration's (FDA) solicitation of public comment on whether use of the term "fresh" should be permitted in labeling foods processed with technologies to control foodborne pathogens, and on what type of criteria FDA should employ when considering the propriety of the term to describe such processed foods. See generally Food Labeling; Use of the Term "Fresh" for Foods Processed With Alternative Nonthermal Technologies; Public Meeting, 65 Fed. Reg. 41,029 (July 3, 2000).

Tropicana is a leading producer of juice and juice beverage products. Tropicana manufactures, markets, sells and distributes products under such well known trademarks as **TROPICANA PURE PREMIUM, TROPICANA SEASON'S BEST, TROPICANA TWISTER** and (under license from Dole Food Company, Inc.) **DOLE**.

Consistent with its overarching desire to manufacture and distribute juices and juice products of the highest quality -- including safety -- informatively labeled about their salient characteristics so as to afford consumers with clear purchasing choices, Tropicana takes a keen interest in this rulemaking. FDA's consideration of the propriety of, and criteria for, use of "fresh" claims in labeling foods processed with alternative technologies to control pathogens raises a number of interesting and interrelated issues with respect to juices. In sum, and as more fully discussed below, we believe:

1. FDA should require the use, and encourage the development, of processing technologies that achieve a 5-log reduction in the most resistant pathogen of public health significance for a juice.

2. Juices subjected to any particular food safety processing technology should not be permitted to be labeled as “fresh” without qualification unless all juices subjected to food safety processing technology are permitted to use the term; however, qualified and non-misleading “fresh” claims should be allowed in describing these products.
3. “Pasteurized” should be recognized as a qualifying term permitted to indicate that a juice or other food has been subjected to any processing technology that results in requisite pathogen reduction.

I. DISCUSSION

A. Foodborne Pathogen Reduction Processing Technologies

Fresh juice is not safer juice -- a fact often overlooked by consumers who view the fresh product as being necessarily better than processed (e.g., pasteurized) juice. FDA is endeavoring to better inform consumers about juice safety through promulgation and implementation of a final rule currently requiring the following label warning on juices that have not been processed in a manner that will produce a minimum 5-log reduction in the pertinent microorganism of public health significance likely to occur in the juice throughout the shelf life of the product:

WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

21 C.F.R. § 101.17(g)(2)(ii); see generally Food Labeling; Warning and Notice Statement; Labeling of Juice Products, 63 Fed. Reg. 37,030 (July 8, 1998) (final rule). Moreover, the agency is endeavoring to better safeguard consumer health through its proposed rule to require such pathogen reduction through processing of juices and juice products under a system of preventative control measures applying mandatory Hazard Analysis and Critical Control Point principles. Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice, 63 Fed. Reg. 20,450 (Apr. 24, 1998) (proposed rule). Tropicana applauds and strongly supports these regulatory endeavors.

Juices that are heat pasteurized, including pasteurized orange juice (21 C.F.R. § 146.140), already accord with the goals of mandatory juice HACCP and, as a result, need not bear label warning statements. Thermal pasteurization represents a technology that already is legally approved and widely applied in processing juices for enhanced safety. In the context of

“fresh” labeling, FDA presently is examining alternative processing technologies to control pathogens in foods, including, but not limited to, high pressure processing, pulsed electric field, pulsed light, submerged arc, and filtration. 65 Fed. Reg. at 41,030. Tropicana believes that the final report of the Institute of Food Technologists (IFT), “Kinetics of Microbial Inactivation for Alternative Food Processing Technologies,” cited in FDA’s Federal Register notice, credibly summarizes the current state of knowledge regarding these alternative technologies. Importantly, this summary points out areas where current scientific understanding is incomplete and further research is needed. In addition to the shortcomings specified by IFT, Tropicana notes other issues in comparing existing heat pasteurization to the alternative processing technologies, including the absence of a surrogate pathogen to use for the significant and common pathogens (such as E. coli 0157:H7) in verifying the effectiveness of the alternative technologies, as well as capacity, reliability, and scale-up from laboratory studies in commercializing the alternative technologies.

Tropicana believes that all new technologies to advance food safety should be pursued and, once developed and verified as effective, permitted in processing appropriate foods. Some work clearly remains to be done. To encourage research and development of alternative food safety technologies, FDA should refrain from unduly burdening safety-enhanced foods with unwarranted disclosures, and refrain from prohibiting descriptive claims, including “fresh,” that are not misleading as applied to a labeled food. However, consistent with advancing food safety, informative labeling, and basic fairness, FDA should take care to regulate “fresh” claims made on products processed using unproven alternative food safety technologies in a manner that is consistent with, and does not serve to denigrate by comparison, foods processed using proven food safety technology, such as heat pasteurization.

B. “Fresh” Claims for Processed Juices

Under FDA’s current regulation governing use of the descriptive term “fresh,” pasteurized orange juice may not be labeled “fresh,” but pasteurized whole milk may be so labeled because “the term ‘fresh’ used to describe pasteurized whole milk . . . does not imply that the food is unprocessed (consumers commonly understand that milk is nearly always pasteurized).” 21 C.F.R. § 101.95. Pursuant to implementation of mandatory juice HACCP, nearly all juices will be heat pasteurized or, if proven effective, subjected to some alternative food safety processing technology. In this eventuality, it may be reasonable to consider permitting unqualified “fresh” claims on not -from-concentrate juices that are pasteurized or otherwise processed to enhance their safety, based upon the same rationale as currently supports “fresh” claims for pasteurized whole milk. A “fresh” claim, of course, would be misleading and impermissible (21 U.S.C. § 321(a)(1)) on juices processed for purposes other than food safety, including from concentrate juices. This appears to be consistent, for example with not permitting “fresh” claims on pasteurized skim milk, processed to modify fat content. If a “fresh” claim ultimately is permitted for juices processed with any food safety technology, it properly should be permitted for all technologies.

Historically, FDA has taken the position that “fresh” claims are appropriate for processed foods only if such processing does not cause adverse changes in the food’s physical or sensory qualities such as would offend consumer sensibilities that the product is in its raw state. E.g., Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2404 (Jan. 6, 1993). FDA is undertaking the present consideration of “fresh” claims for foods processed with new technologies based upon the contention of manufacturers using these processes that their products maintain the same “fresh” characteristics as the unprocessed counterparts. 65 Fed. Reg. at 41,030. However, IFT’s final report undercuts the contention that the alternative processing technologies have no adverse impact on a food’s nutritional and/or organoleptic qualities and, at a minimum, suggests that further research is needed. Thus, it seems premature to extend “fresh” claims to foods processed with the new food safety technologies.

On the other hand, Tropicana has produced a not-from-concentrate juice that, following a thermal “kill” step, would be considered “fresh” by a typical consumer. If the standard for qualifying to claim “fresh” is ultimately to be that the food safety processing results in no meaningful difference in the physical or sensory qualities of the processed food as compared to its unprocessed counterpart, it would be patently arbitrary to distinguish thermal and nonthermal processing in qualifying under the standard. To the extent that FDA contemplates such a distinction, Tropicana strongly objects. Having acknowledged that unqualified “fresh” claims conceptually might be appropriate for juices processed only to enhance safety through pasteurization or some alternative technology, Tropicana believes that the better policy at this time and until further research is completed is not to extend unqualified “fresh” claims to such processed juices. However, qualified claims, such as “fresh squeezed --- pasteurized,” for a not-from-concentrate pasteurized orange juice should be permitted. Authorizing qualified “fresh” claims of this kind would be fully consistent with FDA’s current regulatory practice of permitting, for example, “packed from fresh tomatoes” claims in labeling tomato concentrates processed directly from raw tomatoes (i.e., not reconstituted), and “fresh broccoli -- treated by irradiation” claims for raw broccoli processed with ionizing radiation to inhibit growth and maturation (see generally 21 C.F.R. §§ 101.95(c)(1)(iv), 179.26). Moreover, such claims, consistent with commercial free speech principles, would provide consumers with useful information to distinguish between products in making purchasing decisions.

C. “Pasteurized”

In connection with allowing any “fresh” claims for products, such as orange juice, processed with a food safety technology, Tropicana urges FDA to authorize use of the term “pasteurized” to indicate the processing, regardless of whether the specific processing employed is heat pasteurization of an alternative technology proven to be equivalently effective. Of course, label specification of the alternative technology employed also should be permitted.

“Pasteurized” is a term consumers already commonly understand to denote a safer food. While FDA historically has limited use of the term to thermal processing (e.g., 21 C.F.R. §§ 146.140(a), 1240.61(b); 63 Fed. Reg. at 20,454), there is no compelling reason to so restrict its use prospectively, especially given consumers’ common recognition and understanding of the term. The definitions of “pasteurization” in both the “Webster’s New Collegiate Dictionary” and the “American Heritage Dictionary of the English Language” include irradiation as a type of pasteurization. The scientific community and the food industry already accept a broader definition of pasteurization. For example, at a December 17, 1996 meeting of the National Advisory Committee on Microbiological Criteria for Foods, Dr. Bill Sperber, Senior Corporate Microbiologist for Cargill, Inc., stated that the food industry defines pasteurization as any process that eliminates all microorganisms except resistant spores in a particular food. According to Dr. Sperber:

[P]asteurization processes are not necessarily limited to heat treatments. Other processes that could eliminate pathogens include proven technologies, such as filtration and irradiation, as well as less developed technologies, such as pulsed electric fields or high pressure treatments. With proper validation, these processes could be used instead of heat treatments, they could then be legitimately defined as pasteurization treatments.

Ms. Jenny Scott, Senior Director of the Food Safety Program for the National Food Processors Association, at the same meeting agreed that pasteurization processes include, for example, irradiation and high pressure processing. Based upon its discussions with several academic food safety experts, Tropicana suggests that the following definition govern use of the term “pasteurized” as regards the “fresh” labeling initiative:

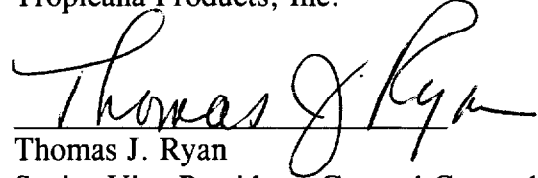
Pasteurization of food is the inactivation of all pathogenic microorganisms that can grow in the food during distribution, retail and use, the elimination or reduction of non-sporeforming spoilage microbes and the inactivation of some enzymes that could cause deleterious effects in food during storage. Pasteurization may be achieved many ways including heat, irradiation, high pressure, pulsed electric field, etc. Typically pasteurized products have a defined refrigerated shelf life. The shelf life of these foods is dependent on the type of food, conditions of pasteurization, packaging and storage conditions.

II. CONCLUSION

Tropicana appreciates the opportunity to comment upon this very important and complex regulatory initiative. We urge the agency to proceed with formulating regulatory law and policy in accordance with the foregoing comments.

Respectfully submitted,

Tropicana Products, Inc.

A handwritten signature in black ink, reading "Thomas J. Ryan". The signature is written in a cursive, flowing style with a horizontal line underneath the name.

Thomas J. Ryan
Senior Vice-President, General Counsel and
Secretary

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